Kinex LLC

New York Manufacturing Extension Partnership

Kinex Pharmaceuticals Becomes cGMP Compliant with Assistance from Insyte Consulting

Client Profile:
Kinex Pharmaceuticals is a drug discovery and development company that is focused on next generation anti-cancer drugs. The company has developed numerous well-known consumer drugs in the pharmaceutical industry. Founded in 2003, Kinex employs 4 people at its facility in Buffalo, New York.

Situation:
Kinex Pharmaceuticals received FDA (Federal Drug Administration) allowance to perform Phase I clinical trials for their first anti-cancer drug, KX2-391. This drug is a kinase inhibitor that has demonstrated efficacy in pre-clinical animal models of colon, pancreatic and prostrate cancers. Over a one-year period the Phase I clinical trials will test the drug in terms of safety, tolerability and pharmacokinetics for about 50 patients with advanced malignancies. Although FDA allowance to perform Phase I clinical trials was viewed as a positive breakthrough for Kinex Pharmaceuticals, there were also concerns that needed to be addressed. The cost, distance and time to develop the drug product were considered to be very significant. This was particularly true if the production of the product was to be outsourced. The company's management staff opted to produce the drug product in house, which was believed to be a preferable option to outsourcing. In order too do so, however, it was necessary for Kinex Pharmaceuticals to meet FDA's current Good Manufacturing Practice (cGMP). The company had limited resources and expertise in-house to address this issue in an expeditious manner. For this reason Insyte Consulting, a NIST MEP network affiliate, was contracted to help drive the cGMP initiative to support the packaging and distribution of the Phase I product.

Solution:
A joint team of Insyte Consulting and the Kinex Pharmaceutical management staff was formed for the purpose of systematically achieving cGMP compliance. The first step was to evaluate the laboratory systems and procedures that were already in place. Where deficiencies were identified, improvements were introduced and documented in written form. As the system was formalized, training was provided in the proper use of the cGMP compliant program. Upon completion of training, a mock production run was conducted in order to validate the integrity of the systems and procedures, as well as identify any possible omissions to the program. Finally, test products were developed with the final documentation in place. This also included an evaluation of the people, processes and equipment prior to the actual production run. Based on this exercise minor modifications were made and some necessary problem solving activities were completed.
Kinex Pharmaceuticals realized several very significant benefits as a result of becoming cGMP compliant. It provided the foundation for the actual Phase I clinical trial and enabled the company to have the trial conducted at two well-renowned test sites, Roswell Park Cancer Institute in Buffalo and M. D. Anderson Cancer Center in Houston, Texas. The cost of the Phase I trial program was reduced

by approximately $150,000 by producing the drug product internally. This enabled the company to hire an additional employee to further accelerate its work. This approach provided Kinex with the flexibility to make product 'on-demand' so they don't need to keep a large inventory. This was very important at the beginning when they didn't know how stable the material was. Additional costs were avoided due to reduced travel, shipping and other related expenses.

Results:
* Achieved cGMP compliance.
* Reduced cost of clinical trial by $150,000.
* Created 1 new job.
* Eliminated large inventory.

Testimonial:
"Insyte Consulting effectively facilitated the process of setting up a cGMP compliant operation and provided the expertise that we did not have internally. As a result we were able to set up an in-house process that saved us more than $150,000 and were able to add an additional employee."
Dr. Lyn Dyster, Vice President